## **RESEARCH ETHICS**

# Right of the living dead? Consent to experimental surgery in the event of cortical death

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Ravelingien *et al* have suggested that early human xenotransplantation trials should be carried out on patients who are in a permanent vegetative state (PVS) and who have previously granted their consent to the use of their bodies in such research in the event of their cortical death. Unfortunately, their philosophical defence of this suggestion is unsatisfactory in its current formulation, as it equivocates on the key question of the status of patients who are in a PVS. The solution proposed by them rests on the idea that it should be up to people themselves to determine when they should be treated as dead. Yet the authors clearly believe (and state) that patients who are in a PVS are in fact dead. Finally, given the public good that their proposal is intended to achieve, the moral importance they place on the consent of a person to the use of his or her body in research is ultimately only defensible in so far as this consent represents the wishes of a living person. It is thus only a gentle caricature of their position to suggest that according to their account, consent to participation in xenotransplantation research is a "right of the living dead". The equivocation by Ravelingien et al on the question of whether these people are living or dead means that they avoid confronting the implications of their argument. The solution proposed by Ravelingien et al to the problem of how we should proceed with xenotransplantation research is therefore not as neat as it first seems to be.

> he unknown magnitude of the risk of xenozoonosis and the difficulties associated with obtaining ethical consent to experimental surgical techniques that offer little prospect of benefit to the patient stand as substantial barriers to the development of safe and effective xenotransplantation.1-4 As xenotransplantation offers the prospect of making life-saving replacement organs available to the tens of thousands of people who currently die each year for want of an appropriate donor organ, there is an urgent necessity to proceed as quickly as possible with research, which may contribute towards the development of safe and effective xenotransplantation. 5 6 i Ravelingien et al<sup>7</sup> are therefore to be congratulated on their contribution to resolving the difficult question on how such research may proceed in an ethical

fashion. Their controversial suggestion is that early human xenotransplantation trials should be carried out on people who are in a permanent vegetative state (PVS) and who have previously granted their consent to the use of their bodies in such research in the event of their cortical death. This would make it possible for xenotransplantation researchers to conduct trials of their treatments on living human bodies and closely monitor the transplant recipients for any signs of xenozoonotic infection or any other unanticipated long-term effects of receiving a xenotransplant, while avoiding the difficult ethical issues that beset any attempts to conduct trials of these treatments on living people. Although they do not discuss it, it seems that the use of the bodies of people who are in a PVS may also advance research into other experimental treatments. which hold out the prospect of major public benefit; yet, they are associated with such a high level of risk and such little hope of benefit to the patient in the initial trials that it would be unethical to conduct them.

Unfortunately, Ravelingien et al's philosophical defence of their proposed solution is unsatisfactory in its current formulation, as it equivocates on the key question of the status of patients who are in a PVS. Ravelingien et al bet each way on the question of whether people who are in a PVS are in fact dead. Their proposed solution rests on the idea that it should be up to people themselves to determine when they should be treated as dead. Yet the authors clearly believe (and state) that patients who are in a PVS are in fact dead. Finally, given the public good that their proposal is intended to achieve, the moral importance they place on the consent of a person to the use of his or her body in this research is ultimately defensible only in so far as this consent represents the wishes of a living person. It is only a gentle caricature of their position to suggest that according to their account, consent to participation in xenotransplantation research is a "right of the living dead".

Although the idea that people should be able to consent to experimental surgery in the event of their entering a PVS remains defensible no matter which of the positions described earlier we eventually settle for, Ravelingien *et al*'s equivocation on the question of whether these

Abbreviation: PVS, permanent vegetative state

<sup>i</sup>This is not to deny that major ethical issues on the use and treatment of sentient non-human animals in xenotransplantation research and practice exist and remain to be resolved.

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people are living or dead means that they avoid confronting the implications of their argument. Each of these alternative positions on the status of patients who are in a PVS has important and somewhat unpalatable implications for the treatment of such patients and for the ethics of carrying out experimental surgery of little expected benefit to the patient in similar cases. The solution that Ravelingien *et al* propose to the problem of how we should proceed with xenotransplantation research is therefore not as neat as it first seems to be.

#### **DEAD OR ALIVE?**

The idea that people should be able to consent to the use of their bodies in xenotransplantation research in the event of entering a PVS is suggested by current practices surrounding organ donation in the event of whole-brain death (Fost,<sup>8</sup> p 96).<sup>11</sup> The proposal made by Ravelingien *et al* is likely to meet with markedly more controversy than existing practices, because the experiments that they propose should be carried out are likely to appear far more grotesque in the public imagination and because the "cadavers" on which these experiments will be performed will be living, breathing bodies.

Ravelingien et al acknowledge that the extension of the notion of death from circulatory death to whole-brain death was itself controversial and that any extension to treat patients in a PVS as dead is likely to be even more so. In anticipation of this controversy, they argue, following a suggestion of Veatch's, that individual and cultural differences in attitudes towards the moment of death should be respected by allowing individual patients to decide for themselves when they should be treated as dead (Ravelingien et al,7 p 96).9 If the patients decide that (for them) death occurs when they have suffered an irreversible loss of consciousness and regardless of whether they continue to have respiration and a pulse even in the absence of mechanical assistance, then they should be able to donate their body to xenotransplantation research just as people may currently donate their body to science in the event of their (circulatory or whole-brain) death. The advantage of this proposal is that it seemingly avoids the necessity of resolving the difficult philosophical and political debates on the status of these patients. It also explains the importance the authors place on gaining the consent of the patient in a PVS for participation in experimental xenotransplantation.

The obvious difficulty with this move is that it is prima facie implausible that whether someone is dead is a matter of individual choice. Although death is a more complex phenomenon than it first appears, especially in the light of advances in medical technology, it remains fundamentally a category of natural science rather than of ethics.10-12 iii As such, it is an objective rather than a subjective matter. To the extent that the definition of death does include making value judgements, these are primarily social rather than individual questions<sup>13-15</sup>; that is, they are questions about how other people should treat and respond to a person in a particular condition. When is it appropriate to bury someone, or to mourn them, or to extract their organs for transplant? These are questions that societies or cultural groups, rather than individuals, have to answer. Indeed, in so far as they necessarily require the disposition and behaviour of large

<sup>ii</sup>Fost also discusses the possibility that we may proceed with sourcing organs from people in a PVS, if they had previously consented to this.

surrounding the definition of death, or the possibility that there is more than one reasonable position on the matter. It is to insist, however, that what the controversy is about is a distinction that has a fundamental role in the life sciences and that requires a definite resolution.

numbers of strangers, they are questions that individuals cannot answer.

Although it may not be possible for individuals to settle the question of when they are dead, it is possible to grant them some power to determine when they should be treated as dead and what can be done to them when they are. This is presumably what Ravelingien et al intend, rather than the stronger and less plausible thesis that individuals should be allowed to determine when they are dead. Yet, even here, there are important limits to people's rights to determine when they should be treated as dead. We do not allow people to decide that their bodies should be available to train medical students in dissection while they are still conscious. for instance. Similarly, in societies that do use a whole-brain criterion of death, although the medical profession may respect the wishes of deceased people not to procure organs from them if they should suffer whole-brain death, they do not typically allow them to insist on continuing ventilation and medical support on the grounds that they are still alive at this point. The question remains then, why cortical death should be held to be within the realm where it is appropriate to allow people to decide whether they should be treated as

The authors suggest, again following Veatch, that people's right to determine when they should be treated as dead should be confined to reasonable claims, with the clear presumption that it is reasonable to treat patients who are in a PVS as either dead or alive (Ravelingien et al, p 96). It is, however, unclear what this restriction on claims about death would amount to, given the range of different opinions on when people are dead. Some religious worldviews believe that dying is a process that does not reach its end until a point long after that at which a person has stopped breathing.<sup>13</sup> Other people, perhaps including a major proportion of the medical community, believe that clearly people are dead when they have no higher cortical functions (Singer,10 p 32-5). 16 17 In an age when human cloning via somatic cell nuclear transfer is close to becoming a reality, cellular death may mark an important point before which there is some hope of resurrecting at least part of what people care about when they think of their mortality. In the face of such wideranging disagreement, it is difficult to settle the bounds of the "reasonable". Indeed, there is almost as large a range of opinion about what the bounds of the reasonable are with regard to beliefs about death as there is about the moment of death itself. Given that death is primarily a matter of natural science and, to a lesser extent, a social consensus, any attempt to settle disagreement on the limits of reasonable beliefs about death must inevitably refer to the matters that underpin claims about death and the social practices that constitute our response to it.13 Pointing to disagreement on the status of patients who are in a PVS therefore only partially mitigates the necessity of settling the question of whether they are dead before we can decide whether it is reasonable to treat them as such.

The real problem, however, with settling questions about the status of patients who are in a PVS by allowing people to decide for themselves when they should be treated as dead is that whatever they decide, they are in fact either dead or alive. Importantly, how we should respond to their desire about how they should be treated depends to some extent on whether they are dead or alive. The wishes of the living and the dead have markedly different moral weights (Machado, 15 p 176) 18. Ravelingien *et al* therefore cannot avoid resolving this question.

#### DEAD?

In fact, Ravelingien *et al* do make it clear at several points in their paper that they believe that a person who is in a PVS is

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in fact dead. To be precise, they believe that cases of PVS present us with a situation in which a person has died, leaving behind a living human body. People in a PVS have lost all those properties or capacities (sentience, rationality and the ability to relate to others) that may plausibly be thought to be constitutive of personhood and to justify the moral respect that people are owed. Moreover, because people in a PVS lack sentience, they no longer possess interests. Consequently, they cannot be harmed in the course of xenotransplantation research (Ravelingien et al,7 p 95). It is merely a strange matter of circumstance that their bodies retain properties such as respiration, circulation and other autonomic nervous reflexes, which are normally associated with people who are alive. Given that people who have entered a PVS are dead, it is reasonably straightforward to conclude that people should be able to will their remains to xenotransplantation research in the event of their cortical death just as they may to other forms of medical research in the event of their whole brain or circulatory death (Ravelingien et al,<sup>7</sup> p 95).

Among a philosophical readership, this conclusion will hardly seem to be surprising. The authors themselves note that the argument that patients who are in a PVS are in fact dead and that consequently their organs should be available to be sourced for transplantation has been made many times before (Rothblatt, p 11; Ravelingien et al, p 95; Singer, 10 p 38–50).8 19 20 But what is now thrown into question is why the authors have restricted the range of cadavers available for xenotransplantation research to those where the recently deceased had provided their explicit consent to their remains being used in such research. Why is it so important that a person's consent has been obtained? At the very least it seems that, in nations that operate an "opt-out" rather than an "opt-in" system of organ collection after death (Machado<sup>15</sup> provides an account of the how different nations in Europe, Australia and North America determine the standard of consent required for organ donation, p 44-7), a strong argument could be made that the bodies of people who are in a PVS should be made available for xenotransplantation research unless they have explicitly directed otherwise. If the benefit to the public of increasing the number of organs available for transplantation justifies a change in the presumption of consent for organ donation, then the same is likely to happen in the case of participation in xenotransplantation research.

#### Moral weight of the wishes of the dead

In fact, the implication of declaring patients who are in a PVS to be dead is more radical. In cases where people do not wish their cadavers to be used for xenotransplantation research, our reason for respecting this desire includes respect for the wishes of the dead. Although there are reasons for respecting the wishes of the dead, these have always been somewhat philosophically controversial, given that the dead will experience no harm if their wishes are not respected (Ravelingien *et al*,<sup>7</sup> p 95–7).<sup>21</sup> This in turn suggests, especially to those with leanings towards utilitarianism, that the interests of the dead should be discounted somewhat when they come into conflict with the interests of the living.<sup>18</sup>

As Ravelingien *et al* have emphasised, the living may have very substantial interests in large numbers of xenotransplantation trials being conducted as quickly as is practicable. It is puzzling then why the authors are so quick to concede that the wishes of the deceased should be allowed to stand in the way of this.

Note that the balance of considerations when using PVS cadavers<sup>iv</sup> in xenotransplantation research, against the wishes of the deceased person, is markedly different from those when collecting organs from patients who have

experienced whole-brain death, which is at issue. Collection of organs from a cadaver may save a few lives at most. Given the revolutionary life-saving potential of xenotransplantation, research on PVS cadavers may save tens of thousands of lives. Indeed, it is precisely because Ravelingien *et al* believe this, that they have put forward their proposal. Of course, drafting any individual PVS cadaver into this research may not save all these lives, but it might well be the case that it will make a more important contribution to the reduction of human suffering than would the use of this cadaver's organs alone. The reasons for co-opting the remains of those who have died by entering a PVS—regardless of their consent—are therefore much stronger than those justifying the sourcing of organs for transplant without consent.

It is true that many societies do give substantial moral weight to the wishes of the deceased about the treatment and disposal of their remains. The public's ideas about what is mandated by the notion of respect for the dead are often much stronger than the justifications usually provided for them by philosophers allow. Despite this, decisions about the treatment of the body of the deceased against the deceased person's wishes are far from unprecedented. It is already firmly established that important and pressing public health interests may override people's wishes about the disposal of their remains. Thus, for instance, when the cause of death of a particular person is unknown but where a dangerous infectious agent is suspected, or when a death has occurred as the result of a criminal act, coroners may require to carry out an autopsy regardless of the wishes of the deceased. On the other hand, as Ravelingien et al point out, some countries, such as New Zealand, allow the relatives of the deceased to override the wishes of the deceased to donate their organs for transplant or research.

Our willingness to override the wishes of the deceased in other circumstances suggests that Ravelingien *et al*'s concern for the consent of the deceased person for the use of their remains is exaggerated. Their belief that patients who are in a PVS are in fact dead, alongside their recognition of the large public benefit that would be achieved by preceding quickly to human xenotransplantation trials, should push them towards the much more radical claim that PVS cadavers should be made available for xenotransplantation research regardless of the wishes of the deceased (Harris, 18 p 125).

#### Respect for the wishes of the relatives?

One obvious and important objection at this point, of course, is that although the wishes of the deceased may be overridden by the benefits to the public of proceeding with xenotransplantation trials, there is also the matter of the wishes of their living relatives. The partner, parents or siblings of the deceased may be understandably distraught at witnessing the still beating heart or working lungs of their recently dead relative being removed from their body and replaced with the organs of genetically modified pigs.

Again, however, there is a familiar range of cases where we neglect the wishes of relatives on the treatment of the remains of the deceased. Ravelingien *et al* themselves note with approval that many countries allow the wishes of the

<sup>iv</sup>It is difficult to know how to refer to the bodies of people who are in a PVS, as their status is the central issue in the controversy under discussion. In this section, however, where I am discussing the possibility that such individuals are dead, "cadavers" does not seem inappropriate

In Victoria, Australia, the circumstances in which autopsies are permitted or required are set out in the Coroners Act 1985. A discussion on the legal status of bodies and the circumstances in which the consent of the person can be overridden in the service of the public interest in the Swedish context is provided by Machado, <sup>15</sup> p 171–83.

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deceased about the disposal of their remains priority over the wishes of their living relatives (p 97; in contrast with the example of New Zealand, which they cite to a different purpose). The interests of other parties may also justify denying the wishes of relatives. We do not allow relatives to discard the body of the deceased in the street or to make ornaments out of it, no matter how strongly they desire to. Remains may be buried or cremated without consulting relatives, if failing to do so will constitute a threat to public health or safety. In cases when public health or the investigation of a possible homicide requires, autopsies may be carried out against the wishes of relatives.

The wishes of living relatives are an important concern when we attempt to assess the balance of considerations surrounding the treatment of the remains of the deceased, but they are not the only consideration. Where the public interest is large enough, we may sacrifice the interests of the relatives for the greater good of the community (Harris, 18 p 125). The harm to the living relatives may be minimised by ensuring that they are aware of the justification for the treatment of the deceased and the good it accomplishes, in the hope that this will cause them to reconsider their opposition to actions taken for this purpose.

#### Public policy reasons for respect for the dead

A major concern about policies on the use of cadavers is the effect that they may have on the willingness of people to donate their remains to science or, more importantly, to enter into a medical or hospital environment at all. If people suspect that their wishes on the disposal of their remains will not be respected after they die, they may be reluctant to remain in hospital if they are dying.

The relative frequency of the PVS compared with circulatory or whole-brain death will, however, have a marked effect on consequentialist calculations about the effects that compulsory requisition of cadavers will have on the living. Policies on the treatment of the cortically dead are likely to affect far fewer people than policies regarding those who have experienced circulatory or whole-brain death. Most people will not end up in a PVS and, to the extent that they recognise this, may judge that what may happen to them if they do enter into such a state is not of sufficient concern to prevent them from seeking medical care when they need it. vi Although the effect of proceeding with xenotransplantation research on PVS cadavers without the consent of the deceased on the willingness of people to enter a medical setting would need to be monitored, there is little reason to believe that this will be so relevant as to outweigh the public benefits to be gained by carrying out xenotransplantation

Another, I think more pressing, concern is that if xenotransplantation was to become associated in the public mind with such macabre practices as transplanting animal organs into the living bodies of the recently deceased against the wishes of the deceased, this may have a disastrous effect on public support and therefore funding for xenotransplantation research. Proceeding with xenotransplantation trials on PVS cadavers without the consent of the deceased (and perhaps also their relatives) would then be self-defeating, as it would undercut support for the very research it was aiming to advance.

This reason for respecting the wishes of the dead about the disposal of their remains, however, depends crucially on empirical facts about the link between experimentation on PVS cadavers and public support for xenotransplantation and on resisting alternative courses of action that may sever this

viThey may also rightly reason that if such experiments are carried out on them they will remain unaware of it and, arguably, unharmed by it.

link. It may simply not happen that public support for xenotransplantation will collapse if the research necessary to prove its safety includes experimenting on deceased people in a PVS against their previously declared wishes. The prospect of resolving the problem of the scarcity of donor organs for transplantation that xenotransplantation holds out may be sufficiently attractive to the public for them to continue to support xenotransplantation research on PVS cadavers even if this takes place against the wishes of those whose remains are being used for this purpose.

More problematically, it may be possible for xenotransplantation research on PVS cadavers to proceed without any effect on popular support for xenotransplantation if the public remains unaware of it. If the expected public benefit from xenotransplantation research is large enough, it seems that researchers may have reason to ignore even the explicit instructions of relatives and proceed with xenotransplantation research on PVS cadavers without their consent and knowledge. That is, they may be justified in proceeding with "clandestine" xenotransplantation research. This may include, for instance, telling the family that their relative had died (and providing them with a body for burial) and then abducting the PVS cadaver for research at a secure location.

The argument here is analogous to an argument that may have been made in favour of the theft of corpses for early medical research and dissection in the 17th, 18th and 19th centuries. The methods used to procure cadavers for dissection, which included theft, deception and perhaps—in some cases—murder, were prima facie immoral.<sup>23</sup> It may well be argued, however, that the apparently immoral actions of these researchers and their body-snatching accomplices were ultimately justified by the immense public benefit that has been secured by modern medicine on the basis of knowledge gained from their activities. Dedicated xenotransplantation researchers may reason that they are in a similar position today. It is normally wrong to deceive people about the fate of their (or their relatives') remains. The benefits of proving xenotransplantation to be safe, however, are so great that if the only way to carry out the necessary trials without xenotransplantation research falling victim to a public backlash that would prevent it from reaching its goals is to do so clandestinely, then such deception may well be justified. The consequentialist tone of Ravelingien et al's paper suggests that they may have difficulty resisting this conclusion (MacDonald,23 p 186-9).vii

Of course, there may be many other good ethical reasons not to pursue this policy. I am not seriously proposing it as a way forward for xenotransplantation research. My purpose in raising the possibility has been solely to show that there is major tension between Ravelingien *et al*'s claims that people who are in a PVS are dead and that there is an enormous public benefit to be gained by carrying out xenotransplantation research on the "living dead" and their claim that it is essential to secure the prior consent of the deceased for participation in such research.

#### **ALIVE?**

One way of justifying the authors' concern for the consent of patients who are in a PVS is to concede that these individuals are still alive. By virtue of the fact that their heart beats and their lungs respire unaided, they are still "one of us"—a living human being and as such a member of a community whose respect for one another in a medical context is expressed in a concern for consent to treatment. In some ways, this is not a terribly attractive philosophical position to hold, given that, as we observed earlier, people who are in a

v<sup>ii</sup>Indeed, recent scandals in the UK suggest that at least some people in the medical and research communities have embraced it. Right of the living dead 605

PVS seem to have so few of the morally relevant properties that ground respect for living human beings. In defence of this position, however, it should be noted that people who are in a PVS legally remain people (Singer, 10 p 27). 20 We also have strong intuitions that despite their lack of sentience, they are—in some sense at least—alive and that for this reason, to experiment on them without their consent while they are in this state is morally more problematic than if they were dead.

If patients who are in a PVS are in fact alive, this need not lead to the conclusion that they may not volunteer their bodies for xenotransplantation trials. It may be argued, for instance, that while they are alive and their previously expressed wishes are worthy of respect because of this, they are also in the unique position of having very few, if any, interests once they are in a PVS. They will not suffer any harm even if participation in xenotransplantation research leads to their death. Thus, as long as they consent to such research taking place, there are no reasons of a paternalistic nature to object to their participation in it. viii

But, any argument that it is legitimate for patients who are in a PVS to consent to participation in xenotransplantation research is likely to lead to further, stronger conclusions about the rights of people to volunteer for experimental surgery, when doing so is unlikely to harm their interests. After all, there are other circumstances in which—it may be argued—people are unlikely to be harmed by participation in experimental research even when it offers little hope of benefit. Most obviously, if people are dying of organ failure, with no prospect of sourcing a human organ for transplant surgery, then receiving a xenotransplant is unlikely to make them worse off. Despite this, they may be willing to consent to participate in research for altruistic reasons in the hope that their participation will help in the development of a technology that will benefit others in the future. If what justifies experimentation on people in a PVS is that they probably will not suffer any harm in the process, then consent to altruistic participation in experimental medical research in cases of medical extremity will also be permissible.ix

This conclusion is not especially surprising in itself. A debate is ongoing about the morality of allowing patients to participate in research that is unlikely to provide them with any benefit if their motives are altruistic. Altruistic participation in research in a situation of medical extremity is also generally recognised to be ethically fraught and to expose people to the danger of exploitation. Further argument is therefore required before we can accept this possible implication of the authors' argument. More importantly, for the purposes of this discussion, the conclusion that it is ethical to allow people to volunteer for participation in research in a situation of medical extremity will remove much of the need for xenotransplantation trials to include people who are in a PVS in the first place, as research into the dangers of xenozoonosis and other long-term health effects on transplant recipients could now be carried out on living patients with their consent.

#### CONCLUSION

None of this discussion is intended as a direct criticism of Ravelingien et al's proposal on how xenotransplantation research may proceed past the current ethical impasse. From a public policy perspective, the proposal that we attempt to secure the consent of people to allow their remains to be used for research purposes should they enter into a PVS is

viiil owe this point to Neil Levy who made it in a seminar at the Centre for Applied Philosophy and Public Ethics, University of Melbourne, at which An Ravelingien et al presented their ideas.

ixThe argument here presumes that harm is measured according to a baseline of interests, which would exist independent of the action being considered

probably the best way of ensuring public support for xenotransplantation research on human bodies in a PVS. The argumentative route that they take to this conclusion is, however, confused. The existence of controversy on the status of people who are in a PVS is itself insufficient to justify the conclusion that it is legitimate to conduct trials on experimental surgery on them so long as their consent is secured. The underlying philosophical question remains the status of these people. If we decide that they are in fact dead, then it seems that the requirement for their consent is weaker than Ravelingien et al indicate and that, given the large public benefit to be gained from developing xenotransplantation technology, we may need to look further at the possibility that research would be justified without the consent of the deceased. If we decide that people in a PVS are in fact alive, then the authors' concern that we seek their consent is well founded. Allowing that such research is ethical suggests that it may also be ethical to proceed with experimental surgery on people consenting to it in other circumstances of medical extremity and, consequently, that the need for xenotransplantation trials to be conducted on poeple who are in a PVS is less pressing than the authors suggest. Major philosophical work therefore remains to be done before we can properly assess the ethics of proceeding to human trials of xenotransplantation on people in a PVS. By drawing attention to the issues, Ravelingien et al have made an important contribution to this project.

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